EXHIBIT 152

E1044.1

From: Cooper, Aimee
Sent: Friday, June 23, 2017 3:19 PM
To: Jones, Heather
Subject: letter you ask for
Attachments: 0427_001.pdf

Thanks,
Aimee

Aimee Cooper
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From: Cooper, Aimee [mailto:Aimee.Cooper@parpharm.com]
Sent: Friday, June 23, 2017 3:12 PM
To: Cooper, Aimee
Subject: Attached Image

Witness: Par - Norton
Exhibit: 10
Date: 1/16/19
Margaret Reihl, CCR, CRR, RPR

Memorandum

Subject
Manufacturer Briefing with Qualitest Pharmaceuticals
[redacted]
(DFN: 601.04.02)

Date
MAR 27 2013

To
Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

From
Barbara J. Boockholdt, Chief
Regulatory Section, ODG
Office of Diversion Control

On March 6, 2013, a meeting was held in Arlington, Virginia at the Drug Enforcement Administration (DEA) Headquarters between DEA and Qualitest Pharmaceuticals (Vintage Pharmaceuticals). Representing Qualitest were: Tracey Hernandez, Director DEA Compliance, Denise Hudson, EVP Enterprise Quality & Supply Chain, and Sanjay Patel, VP Supply Chain Procurement & Logistics, both representatives from Qualitest's Philadelphia location via telephone conference call. Representing DEA were: Staff Coordinator (SC) Leonard Levin and James Arnold, Unit Chief both from the Regulatory Section (ODGR) and GS Patricia Millier from the Birmingham District Office. The purpose of the meeting was to address the manufacturing and distribution practices of controlled substances by Qualitest. SC Levin stated he would be concentrating on oxycodone 15mg & 30mg tablets and hydrocodone 10/325mg & 10/500mg tablets. Qualitest holds the following five DEA Registrations as a manufacturer: [redacted] and holds one DEA Registration number [redacted] as a distributor of Schedules II-V controlled substances.

SC Levin opened the meeting by stating its purpose was both educational and informative. SC Levin stated he would discuss Qualitests' responsibilities under the Controlled Substances Act (CSA), their Suspicious Order Monitoring System (SOMP), their procedures concerning due diligence, knowing their customers, who their customers sell to, and graphs depicting the pharmacies and practitioners where oxycodone 15mg & 30mg tablets and hydrocodone 10/325mg & 10/500mg tablets were ultimately dispensed from.

SC Levin asked Ms. Hernandez to talk briefly about Qualitest, their product line, and their suspicious order monitoring system. Ms. Hernandez stated that Qualitest is a manufacturer of controlled and non-controlled substances. Qualitest has locations in Huntsville, AL, Westbury, NY, Charlotte, NC and Philadelphia, PA. Ms. Hernandez was aware of the charge back system utilized by manufacturers, including Qualitest, but stated to date the firm has not reviewed it. Ms. Hernandez stated the firm's suspicious order monitoring system is a work in progress and it is currently based on historical purchases by an individual customer (thresholds). Ms. Hernandez stated that Qualitest does not routinely visit their customers to determine who they are selling to and Qualitest does not visit their pharmacies or

practitioners who dispense their products. Ms. Hernandez stated the only individuals who visit their customers are from the sales force and not compliance. Ms. Hernandez stated Qualitest is currently seeking to update their computer system and to improve their suspicious order monitoring system. A copy of the flow chart showing Qualitest' s parent company Endo Health Solutions Inc. and its subsidiaries are attached. Ms. Hernandez stated that over 50 percent of the firm's sales are controlled substances. The bulk of Qualitest's controlled substances are in dosage form tablets. Qualitest does not sell directly to pharmacies or practitioners. They sell solely to manufacturers and distributors.

SC Levin spoke of the current epidemic of prescription drug abuse in the United States (US). SC Levin stated that 80 percent of all controlled substances manufactured in the world are prescribed and consumed in the United States. SC Levin stated that the abuse and diversion of oxycodone 15mg & 30mg tablets is a major problem. SC Levin discussed the pain clinic issues found in Florida, as well as, other drug abuse trends around the country. SC Levin outlined the methods of diversion of these products and advised that Qualitest is responsible for monitoring and reviewing their suspicious order monitoring system, assuring Qualitest is reporting to ARCOS correctly, visiting, and knowing their customers, maintaining a due diligence file on their customers, and knowing where their products are ending up. SC Levin reviewed the DEA Diversion web-site concerning checking the legitimacy of DEA registrations, reporting theft or loss of controlled substances, renewing registrations, and reviewing pertinent closed investigations by DEA on DEA registrants.

SC Levin presented a PowerPoint presentation exemplifying the common characteristics and issues associated with the distribution and manufacturing of controlled substances. SC Levin stressed the importance of a manufacturer's due diligence requirements, knowing one's customers, and the detection of suspicious orders. Specifically reviewed were the following:

- Supreme Court Cases and Immediate Suspension Orders
- Closed System of controlled substance distribution
- Establishing the medical necessity for a prescription and/or a distribution to be legal
- The DEA Internet Policy and the Ryan Haight Act
- Policies published by the American Medical Association (AMA) and the Federation of State Medical Boards (FSMB)
- Review of Suspicious Order requirements of Title 21, Code of Federal Regulations
- Knowing one's customer
- Theft and loss reporting
- Recent News Articles regarding actions taken against CVS pharmacies, Cardinal, Walgreens
- System to insure the address, controlled substance schedules and expiration date of customers' DEA Registrations prior to shipping them controlled substances
- Recent actions taken by the DEA to suspend or revoke controlled substance registrations of distributors and pharmacies who continue to divert controlled substances into the illicit market

At the conclusion of the PowerPoint presentation, SC Levin presented graphs documenting the distribution of oxycodone 15mg & 30mg tablets and hydrocodone 10/325mg & 10/500mg tablets by Qualitest. These distributions were derived from ARCOS reports submitted by Qualitest under specific NDC numbers. The graphs revealed several pharmacies purchasing large quantities of oxycodone and hydrocodone products from Qualitests' customers. The graphs show that pharmacies in Florida purchased very large quantities of Qualitests' oxycodone products. Also, the graphs show that pharmacies in Texas and California purchased large quantities of Qualitests' hydrocodone products.

Ms. Hernandez, Ms. Hudson, and Mr. Patel were completely unaware of where Qualitests' products were ending up. Mr.Patel, Ms. Hudson and Ms. Hernandez stated they had never seen their sales presented in format form before.

SC Levin explained that this meeting was to inform, educate, provide pertinent ARCOS data, cover national trends on drug abuse and diversion, and to discuss the pain management epidemic in Florida involving oxycodone. DEA is seeking to partner with drug distributors and manufacturers in resolving this problem. SC Levin stated should Qualitest or any firm who had been briefed was found to have violated the CSA pertaining to what was discussed during the course of this meeting; DEA could seek administrative or civil action to remedy the violations. SC Levin stated that Qualitest must review the charge back information which they have access to, immediately address deficiencies in their suspicious order monitoring system, have compliance people visit their customers to review their suspicious order monitoring system and review the top customers of their customers and pay visits to pharmacies that purchase their products. SC Levin advised Ms. Hernandez that Qualitest must know their customers and maintain a due diligence file on them. SC Levin stated Qualitests' current system as explained to him and as seen on their ARCOS data is inadequate to say the least. SC Levin told Ms. Hernandez to educate Qualitest employees who have access to controlled substances on what was discussed today and communicate with her local DEA office should she have any questions.

At this time, SC Levin asked if there were any questions. There were none. The meeting between the Drug Enforcement Administration and Qualitest Pharmaceuticals was concluded.

Attachments:

1. PowerPoint Presentation
2. Graphs of Qualitest' s ARCOS sales and purchases
3. Flow chart of Qualitest' s ownership
4. Qualitest' s DEA registrations

cc: GS Patricia Millict, Birmingham District Office